IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-672-JCJ
	)	
LUPIN LIMITED and	)	
LUPIN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

ANSWER OF DEFENDANTS
LUPIN PHARMACEUTICALS, INC. AND LUPIN LIMITED

Defendants Lupin Pharmaceuticals, Inc., having its principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202, and Lupin Limited, having its principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India (collectively "Lupin"), by and through their attorneys, respond to each of the numbered paragraphs to the Complaint filed against it by Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott") as follows:

THE PARTIES

1. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and, therefore denies them.

2. Lupin admits the allegations set forth in paragraph 2 of the Complaint.

3. Lupin admits the allegations set forth in paragraph 3 of the Complaint.

4. Lupin admits that Lupin Pharmaceuticals, Inc. distributes generic drugs for sale and use in the State of Delaware. Lupin denies the remaining allegations made in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Lupin admits that this action for alleged infringement of U.S. Patent No. 6,667,050 ("the '050 patent") purports to arise under the patent laws of the United States, and that subject matter jurisdiction is proper for the claims directed against Lupin Ltd. only. Lupin denies that subject matter jurisdiction exists over the claim of infringement based on 35 U.S.C. §271(e) insofar as it is directed to Lupin Pharmaceuticals Inc.. To the extent there are any remaining allegations in paragraph 5 of the Complaint, Lupin denies them.

6. For the purposes of this action only, Lupin Ltd. and Lupin Pharmaceuticals Inc. do not contest personal jurisdiction, but deny the remaining allegations in paragraph 6 of the Complaint.

7. Lupin denies the allegations set forth in paragraph 7 of the Complaint.

8. Lupin does not contest that venue is proper as to it in this Court, but denies the remaining allegations in paragraph 8 of the Complaint.

COUNT I
CLAIM FOR INFRINGEMENT OF THE '050 PATENT

9. On information and belief, Lupin admits that Warner Chilcott is the holder of New Drug Application ("NDA") No. 21-490, for Femcon® Fe (previously Ovcon® 35 Fe), which contains the active ingredients norethindrone and ethinyl estradiol in a chewable tablet form. On information and belief, Lupin admits that Femcon® Fe was approved by the United States Food and Drug Administration on ("FDA") on November 14, 2003 and is indicated for the prevention of pregnancy in women who elect to use it as

a method of contraception. Upon information and belief, Lupin admits that Femcon® Fe is sold as an oral contraceptive that contains 21 chewable tablets comprising 0.4 mg norethindrone and 0.035 mg ethinyl estradiol followed by 7 ferrous fumarate tablets. To the extent there are any remaining allegations in paragraph 9 of the Complaint, Lupin denies them.

10. Lupin admits that U.S. Patent No. 6,667,050 ("the '050 patent") entitled "Chewable Oral Contraceptive" was issued by the United States Patent and Trademark Office ("PTO") on December 23, 2003 and that a copy of the '050 patent is attached as Exhibit A to the Complaint. Lupin denies that the '050 patent was "lawfully" issued by the PTO.

11. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of the Complaint.

12. On information and belief, Lupin admits that the '050 patent claims a chewable, palatable oral contraceptive tablet, a method of administering said tablet to a human female and a method of enhancing compliance with a human female oral contraceptive regimen. To the extent there are any remaining allegations in paragraph 12 of the Complaint, Lupin denies them.

13. Lupin admits that the '050 patent is listed in the FDA *Approved Drug Products with Therapeutic Evaluations* ("Orange Book") for Femcon® Fe. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 13 of the Complaint, and, therefore, denies them.

14. Lupin admits that Lupin Ltd. (not Lupin Pharmaceuticals, Inc.) submitted to the FDA an Abbreviated New Drug Application ("ANDA") filed under 21 U.S.C. §355(j), to obtain approval to engage in the commercial manufacture, use, or sale of a product comprising 21 tablets containing 0.4 mg norethindrone and 0.035 mg ethinyl estradiol with 7 ferrous fumarate tablets. To the extent there are any remaining allegations in paragraph 14 of the Complaint, Lupin denies them.

15. Lupin admits that Lupin Ltd.'s ANDA directed to its proposed product comprising 21 tablets containing 0.4 mg norethindrone and 0.035 mg ethinyl estradiol with 7 ferrous fumarate tablets has been assigned No. 91-332. To the extent there are any remaining allegations in paragraph 15 of the Complaint, Lupin denies them.

16. Lupin admits that the composition that is the subject of Lupin Ltd.'s ANDA contains 21 chewable tablets comprising 0.4 mg norethindrone and 0.035 mg ethinyl estradiol followed by 7 tablets containing ferrous fumarate in a chewable, palatable tablet form for oral contraception in a human female. To the extent there are any remaining allegations in paragraph 16 of the Complaint, Lupin denies them.

17. Lupin admits the allegations sets forth in paragraph 17 of the Complaint with respect to Lupin Ltd.. To the extent there are any remaining allegations in paragraph 17 of the Complaint against Lupin Pharmaceuticals, Inc., Lupin denies them.

18. Lupin admits that Lupin Ltd. (not Lupin Pharmaceuticals, Inc.) sent notice of a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act to Warner Chilcott on or about July 30, 2009. On information and belief, Lupin admits the remaining allegations in paragraph 18 of the Complaint.

19. Lupin denies the allegations in paragraph 19 of the Complaint.

20. Lupin denies the allegations in paragraph 20 of the Complaint.

21. Lupin denies the allegations in paragraph 21 of the Complaint.

DEFENSES

Further responding to the Complaint, and as additional defenses thereto, Lupin asserts the following defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming any burden when such burden would otherwise be on Warner Chilcott.

FIRST DEFENSE
(Invalidity of the '050 Patent)

22. In view of the allegations of infringement contained in the Complaint, one or more of the claims of the '050 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example and not of limitation, any claim construed so as to be infringed by Lupin would be invalid under 35 U.S.C. §§ 102 or 103.

SECOND DEFENSE
(Non-infringement of the '050 Patent)

23. The manufacture, use, offer for sale, sale, or importation of the Lupin products that are the subject of ANDA No. 91-332 does not and will not infringe one or more claims of the '050 patent, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(Improper Party)

24. Lupin Pharmaceuticals, Inc. is not a proper party to this action at least because it did not file ANDA No. 91-332.

PRAYER FOR RELIEF

WHEREFORE, Lupin respectfully requests the Court enter judgment against Plaintiff and Counter-Defendant Warner Chilcott to include:

(a) dismissal of Warner Chilcott's complaint with prejudice;

(b) denial of each of Warner Chilcott's requested forms of relief against Lupin;

(c) an award to Lupin of its reasonable costs and attorney's fees and expenses in connection with this action; and

(d) such other and further relief as the Court may deem just and proper..

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on October 21, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on October 21, 2009, the attached document was Electronically Mailed to the following person(s):

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